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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,088

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GOJKOVIC3

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EXAMINER

KOSSON, ROSANNE

ART UNIT

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1652

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,088	Applicant(s) GOJKOVIC, ZORAN	
	Examiner Rosanne Kosson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,9-22,26-50,55,57-59,61,63-72 and 76 is/are pending in the application.
- 4a) Of the above claim(s) 10-15,17,18,21,26-43 and 46-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,9,16,19,20,22,55,57-59,61,63-72 and 76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on January 26, 2009 has been received and entered. Claims 1, 2, 59, 61 and 64 have been amended. Claims 3, 8, 23-25, 44-45, 60, 51-54, 56, 60, 62 and 73-75 have been canceled. Claim 76 has been added. As discussed in the previous Office actions, claims 10-15, 17, 18, 21 and 26-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Accordingly, claims 1, 2, 4-7, 9, 16, 19, 20, 22, 55, 57-59, 61, 63-72 and 76 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 7, 55 and 65 are objected to because of the following informalities. Appropriate correction is required.

In claim 7, the term "sequence presented as SEQ ID NO:1" should be changed to "sequence of SEQ ID NO:1."

In claim 55, the comma between claim 1 and encoding said enzyme (end of line 3) should be deleted to make it clear that the word "encoding" refers to the "polynucleotide of claim 1." If the comma remains, it appears as if "encoding" is another step of the method as are the "culturing" and recovering steps.

In claim 65, the terms "c)" and "d)" should be a) and b) or deleted.

Claim Rejections - 35 USC § 112, second paragraph

In view of Applicants' amendments to the claims, the rejections in the previous Office action are withdrawn. Upon reconsideration of the claims, however, the following rejections apply.

Claims 1, 2, 4-7, 9, 16, 19, 20, 22, 55, 57-59, 61, 63-72 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1b, 6 and 65 recite the term "complement" of the polynucleotide of claim 1(a). This term is indefinite, because it reads on any fragment of the full-length complementary sequence. As a result, it is unclear whether Applicant means the full-length complementary sequence or any fragment thereof. Appropriate correction is required. These claims should be amended to recite the "full-length complement."

Claims 6 and 65-68 recite the terms medium, medium/high, high and very high stringency conditions. These terms are indefinite because there is no definition in the specification of which polynucleotides are actually encompassed by these terms. A cursory review of the specification (see p. 10) shows that exemplary conditions for these stringencies are disclosed, but these are not a definition of the conditions which are encompassed by the terms medium, medium/high, high and very high stringency. Thus, these terms are indefinite, because the art recognizes no single set of conditions as medium, medium/high, high and very high stringency conditions. What may be highly stringent conditions for researcher X may not be for researcher Y. Appropriate correction is required. For example, the claims may be amended to recite actual hybridization and washing conditions in the claims, so long as these are supported in the specification. Applicant should note that claim 6 recites a subgenus (polynucleotides of claim 1 that hybridize under medium stringency conditions to the

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complement of SEQ ID NO:1), and one cannot determine which species are in this subgenus, because medium stringency conditions are undefined.

Moreover, because the hybridization conditions in claims 65-68 are considered to be undefined, and are, therefore, any hybridization conditions, the following art rejection applies.

Claim Rejections - 35 USC § 102

Claims 65-68 are rejected under 35 U.S.C. 102(a) as being anticipated by Knecht et al. ("Mosquito has a single multisubstrate deoxyribonucleoside kinase characterized by unique substrate specificity," *Nucleic Acids Res* 31(6):1665-1672, March 2003). As discussed in the previous Office actions, Knecht et al. disclose a polynucleotide encoding a polypeptide that is a mosquito deoxyribonucleoside kinase that has 81.4% sequence identity to SEQ ID NO:2 (202 of 248 amino acids). See p. 1669, right col., and p. 1670, Fig. 3.

The specification discloses that medium stringency washing conditions are 60 °C, medium/high stringency washing conditions are 65 °C, high stringency washing conditions are 70 °C and very high stringency washing conditions are 75 °C. Under the medium to high stringency conditions exemplified (2XSSC and 60 °C, 65 °C and 70 °C), the polynucleotides that hybridize will have approximately 65%-75% sequence identity to the polynucleotide of SEQ ID NO:1, using the equation of Meinkoth and Wahl (see Current Protocols in Molecular Biology, Hybridization Analysis of DNA Blots, pp. 2.10.8-2.10.11, 1993): $T_m = 81.5\text{ °C} + 16.6 \times \log_{10}[\text{Na}^+] + 0.41 \times (\%GC) - .61 \times (\%\text{form}) - 500/L$. This equation calculates the T_m and how much structural variability is associated with specific hybridization/wash conditions. Under Applicant's conditions, T_m is approximately 95 °C ($= 81.5\text{ °C} + 16.6 \times \log_{10}[\text{Na}^+ = 3.9/10] + 0.41 \times (\%GC=50) - .61 \times (\%\text{form}=0) - \text{neglect } 500/L$). A % GC of 50% is assumed, no formamide is in the system, and one can neglect 500/L where L is the length of the polynucleotide to hybridize

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to the target. $[Na^+]$ for a 20X SSC solution is 3.9. Therefore, in this case, $[Na^+]$ is 0.39. The difference in T_m and the temperature at which the washing takes place gives the % mismatching between the target and the probe, because T_m is reduced by approximately 1 °C for each 1% mismatching. Therefore under the conditions recited when T is 60 °C, there is 35% mismatching ($= 95 - 60$ °C), when T is 65 °C, there is 30% mismatching ($= 95 - 65$ °C), and when T is 70 °C, there is 25% mismatching ($= 95 - 25$ °C). Thus, at 2X SSC and 60 °C, the hybridizing polynucleotides have 65% sequence identity to the target, at 2X SSC and 65 °C, 70% sequence identity to the target, and at 2X SSC and 70 °C, 75% sequence identity to the target. Because these calculations are approximations, and the polynucleotide of Knecht et al. has 72% sequence identity to SED ID NO:1 ($72 = 538 \text{ matches} \times 100/747$; SEQ ID NO:1 = 747 bp), it is very likely that the polynucleotide of Knecht et al. will hybridize at 2X SSC and 65 or 70 °C, which corresponds to Applicant's example of medium/high and high stringency conditions. Therefore, claims 65-67 are anticipated by the prior art. Claim 68 is rejected as well, because the hybridization conditions are considered to be undefined.

In reply to Applicant's comments, regarding the restriction requirement, the restriction requirement has been discussed in each Office action and its finality was reinforced in the previous Office action. Regarding rejoinder of certain method claims under the doctrine of *In re: Ochiai*, as discussed in the restriction requirement Office action, claims to methods of using the claimed polynucleotides that are of the same scope as allowable polynucleotide claims will be considered for rejoinder when all elected product claims are allowable. Withdrawn process claims that are not commensurate in scope with an allowable product claim **will not be rejoined**. See MPEP § 821.04(b). Applicant is reminded that to be allowable, the rejoined claims must meet **all** criteria for patentability including the requirements of 35 U.S.C. 101, 102,

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103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. To advance prosecution, Applicants may wish to reevaluate claims such as claim 36, which recites a method of treating any animal suffering from any pathogenic disease. Regarding an Examiner's Amendment, Applicant may amend all of his withdrawn claims at any time, as these claims are not under examination. Putting the claims into condition for allowance is Applicant's responsibility. Applicant should not expect an Examiner's Amendment to finish the prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2009-02-06
/Delia M. Ramirez/
Primary Examiner, Art Unit 1652

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